Inspection report on compliance with HTA licensing standards
Inspection date: **18 August (remote) and 27 August (site visit) 2025**

King's College Hospital

HTA licensing number 12378

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation
King's College Hospital Denmark Hill	Licensed	Not licensed

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that King's College Hospital ('the establishment') had met the majority of the HTA's standards, 9 minors shortfalls were found against standards for Governance and quality systems and Premises, facilities and equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being

implemented to meet the shortfalls identified during the inspection.

Compliance with HTA standards
All applicable HTA standards have been assessed as fully met.

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
c) There are change control mechanisms for the implementation of new operational procedures.	The establishment did not have a system in place to ensure that change control mechanisms were applied for the implementation of new operational procedures. At the time of inspection, there were no documented records showing implementation of operational procedures.	**Minor**
e) There is a system for managing complaints.	The establishment did not have a system in place for the management of complaints related to activities regulated by the HTA. At the time of inspection, there was no documented process describing how complaints should be received, recorded, investigated, and resolved.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	The establishment did not have a documented schedule of audits covering licensable activities. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.	The establishment had no evidence of audits and there were no audit findings to assess. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	The establishment did not have documented risk assessments for practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

b) Risk assessments are reviewed regularly.	There were no documented risk assessments in place to be reviewed. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
c) Staff can access risk assessments and are made aware of risks during training.	There were no documented risk assessments for staff to access. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

PFE1 The premises are secure and fit for purpose		
c) There are documented cleaning and decontamination procedures.	The establishment did not have documented cleaning and decontamination procedures. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue		
d) There are documented contingency plans in place in case of failure in storage area.	The establishment did not have documented contingency plans in place in the event of a failure in the storage area. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Background

King's College Hospital is licensed for the storage of relevant material which has come from a human body for use in a scheduled purpose, under the Human Tissue Act 2004 (HT Act). Human samples are stored for use in the scheduled purpose of 'research in connection with disorders, or functioning, of the human body'. The establishment is functioning as a Research Tissue Bank (RTB) with recognised Research Ethics Committee approval. King's College Hospital has been licensed by the HTA since February 2007. This was the fourth inspection of the establishment; an evaluated self-assessment took place in April 2025. Since the previous inspection, there have been five CLH Name Contact changes, change of DI and appointment of two new PDs.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the inspection:

Standards assessed against during inspection
There are 47 standards in the Research sector, of which 46 were assessed (standards published 3 April 2017). Standard PFE2(b) could not be assessed as the establishment does not store bodies or body parts

Review of governance documentation
The assessment included a review of documentation relevant to the establishment's licensed activities. This included policies and procedural documents relating to licensed activities, agreements with suppliers, equipment maintenance records, arrangements for temperature monitoring for the storage units and a review of the sample tracking system.

Visual inspection
The site visit included a visual inspection of areas where samples were stored, this included a review of the areas where RTB material is stored in freezers.

Audit of records
During the visual inspection, records for 14 stored samples were reviewed. These were located in -80°C freezers, and full traceability was confirmed for all items audited.

Meetings with establishment staff
The inspection included discussions with the Designated Individual (DI), with Person Designated and Quality Assurance Manager.

Report sent to DI for factual accuracy: 11 September 2025
Report returned from DI: 26 September 2025
Final report issued: 02 October 2025

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004 (HT Act) or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or

- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with the final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.